

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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BRISTOL-MYERS SQUIBB COMPANY)	
and KOSAN BIOSCIENCES INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 09-1330 (EGS)
)	(consolidated with Civ. No 09-2420)
DAVID KAPPOS, in his official)	
capacity as Under Secretary)	
of Commerce for Intellectual)	
Property and Director of the)	
United States Patent and)	
Trademark Office,)	
)	
Defendant.)	
)	

MEMORANDUM OPINION

This case is before the Court on defendant’s motion for reconsideration of the Court’s January 27, 2012 Memorandum Opinion and Order granting plaintiffs’ motion for summary judgment and denying defendant’s motion to dismiss. Upon consideration of the motion, the response and reply thereto, the entire record, the applicable law, and for the reasons set forth below, the defendant’s motion for reconsideration is **DENIED**.

I. INTRODUCTION

Plaintiffs Bristol-Meyers Squibb Company and Kosan Biosciences Inc. filed this action on June 17, 2009 seeking review of certain patent term adjustments granted by the Director of the United States Patent and Trademark Office

("PTO"). Plaintiffs alleged that all of the challenged PTO patent term adjustment determinations relied on an erroneous interpretation of 35 U.S.C. § 154(b), rejected by the United States Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Amended Complaint identified twenty-one patents, set forth in twenty-one separate counts, for which the PTO allegedly incorrectly determined the patent term adjustment.

In June 2010, the Court ordered thirteen of the twenty-one patents identified by plaintiffs in this action to be remanded to the PTO for recalculation and adjustment of the patent terms in accordance with *Wyeth*. Court's Minute Order of June 23, 2010. Eight counts remained as of January 27, 2012.¹ The parties agreed that the timeliness of plaintiffs' appeals for the remaining Counts was the sole remaining legal question. See *id.* at 3.

On January 27, 2012 the Court granted plaintiffs' cross-motion for summary judgment and denied defendant's motion to dismiss, finding that plaintiffs' appeals of certain patent term adjustments were timely filed because the statute of limitations

¹ Those counts were Count Five, Count Six, Count Eleven, Count Thirteen, Count Seventeen, Count Eighteen, Count Nineteen, and Count Twenty. In addition, Civil Action Number 09-2420, *Bristol-Meyers Squibb Company v. Kappos*, was consolidated with this action. Count Four was the remaining Count in that action as of January 27, 2012. See January 27, 2012 Memorandum Opinion ("Jan. 27 Op.") at 2.

for filing such an action was tolled by plaintiffs' request that the PTO reconsider its patent term adjustment decisions. See ECF No. 41. Defendant moved for reconsideration of the Court's decision on February 24, 2012 and the Court held oral argument on the motion on July 10, 2012. The motion is now ripe for the Court's determination.

II. BACKGROUND²

Patents are ordinarily granted "for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States. . . ." 35 U.S.C. § 154(a)(2). If the PTO causes certain delays in the processing of the patent, however, a patent's term may be extended. 35 U.S.C. § 154(b)(1). The statute provides for the adjustment and calculation of patent terms as a result of several different categories of delay.

At issue in this case are two of those categories: "A Delay" and "B Delay." The "A Delay" is the delay of the PTO to meet certain intermediate deadlines during the pendency of a patent application. 35 U.S.C. § 154(b)(1)(A). The "B Delay" is the delay caused by the PTO's failure to issue the patent within

² The factual and procedural background of this case has been discussed more fully in the Court's January 27, 2012 Opinion. See ECF No. 41. Accordingly, the factual and procedural background will be discussed herein only to the extent necessary to resolve the pending motion for reconsideration.

three years of the date of the filing of the patent application.
35 U.S.C. § 154(b)(1)(B).

After the PTO makes a determination that a patent application will be granted, it issues a written notice of allowance of the application. *Id.* § 151. Also issued with the notice of allowance is an initial determination of the patent term adjustment, if applicable. 35 U.S.C. § 154(b)(3)(B)(i) (requiring the PTO to "make a determination of the period of any patent term adjustment" and "transmit a notice of that determination with the written notice of the allowance of the application"). If an applicant disagrees with a patent term adjustment determined by the PTO, it is entitled to request reconsideration of the patent term adjustment. 35 U.S.C. § 154(b)(3)(B)(ii).

Because the patent term adjustment submitted with the notice of allowance is issued months before the grant of the patent, the patent term adjustment reflected in the notice of allowance does not include "B delay," because "B Delay" continues to accrue until the grant of the patent. As the PTO explained in its motion to dismiss:

Because the computer program that the USPTO uses to calculate the PTA does not calculate "B Delay" until the patent issue date is determined, this initial PTA determination typically only includes the "A delay" determined by the USPTO as of the date of the notice of allowance. Thus, at this point, the applicant is

only able to challenge the USPTO's A-delay determination.

Def.'s Mot. to Dismiss at 3, ECF No. 28. The regulations provide that any requests for reconsideration of the patent term adjustment indicated in the patent when it is granted must be made within two months of the date that patent issues. 37 C.F.R. § 1.705(d).

Section 154 permits the applicant to appeal the patent term adjustment to a United States District Court. The statute provides:

An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia³ within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to any such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

35 U.S.C. § 154(b)(4)(A).

In its January 27, 2012 Opinion, the Court addressed the remaining issue of whether the plaintiffs' appeals of the patent term adjustments were timely filed. The Court discussed the general tolling rule as applied to agency decisions and the Supreme Court's decision in *Interstate Commerce Commission v.*

³ Effective September 16, 2011, the United States District Court for the Eastern District of Virginia replaced the United States District Court for the District of Columbia as the appropriate court for any civil action commenced on or after that date.

Brotherhood of Locomotive Engineers, 482 U.S. 270 (1987). The Court also explained the basis of the tolling rule, which is that “[a] request for administrative reconsideration renders an agency’s otherwise final action non-final with respect to the requesting party.” *Clifton Power Corp. v. FERC*, 294 F.3d 108, 110 (D.C. Cir. 2002) (citing *United Transp. Union v. Interstate Commerce Comm’n*, 871 F.2d 1114, 1116 (D.C. Cir. 1989)). If the agency action is non-final, the district court lacks jurisdiction to review it, and the time to challenge that agency decision in court must be tolled.

The Court explained that the tolling rule set forth in *Locomotive Engineers* has been nearly universally applied, and the Court noted that defendant conceded that the rule would apply in this case unless the patent statute would be “expressly contravened by the tolling rule.” Jan. 27 Op. at 11 (quoting Def.’s Combined Opp’n at 8). The Court discussed one case in which tolling was found not to apply, *Stone v. INS*, 514 U.S. 386 (1995). The Court summarized the facts and holding of *Stone*, which found that the tolling rule did not apply to an action challenging a deportation order under the Immigration and Nationality Act (“INA”). Finding that “[n]othing in the patent statute is comparable to the INA language that prevented the application of the general tolling rule in *Stone*,” this Court held that the tolling rule applied to plaintiffs’ motions for

administrative reconsideration of the patent term adjustments, and therefore, plaintiffs' appeals in this Court were timely filed. The Court further explained that the application of the tolling rule in this case is not only consistent with the statutory language, but also the function of the tolling rule itself, which seeks to conserve judicial resources.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 59(e) allows a party to file a Motion for Reconsideration, but such motions "are disfavored and relief from judgment is granted only when the moving party establishes extraordinary circumstances." *Niedermeier v. Office of Baucus*, 153 F. Supp. 2d 23, 28 (D.D.C. 2001) (citing *Anyanwutaku v. Moore*, 151 F.3d 1053, 1057 (D.C. Cir. 1998)). A motion for reconsideration is not a second opportunity to present argument upon which the court has already ruled. *W.C. & A.N. Miller Cos. v. United States*, 173 F.R.D. 1, 3 (D.D.C. 1997). "A Rule 59(e) motion is discretionary and need not be granted unless the district court finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." *Firestone v. Firestone*, 76 F.3d 1205, 1208 (D.C. Cir. 1996) (internal citations omitted). In addressing the claims of a party on a motion for reconsideration, the Court is free to expand upon or clarify the reasons supporting its

prior ruling. *Dage v. Johnson*, 537 F. Supp. 2d 43, 49 (D.D.C. 2008); see *Payne v. District of Columbia*, 808 F. Supp. 2d 164, 172-73 (D.D.C. 2011).

IV. DISCUSSION

In its motion for reconsideration, the PTO alleges that the Court misapprehended a "critical distinction" regarding the difference between the patent term adjustment statute and other statutes in which courts have found *Locomotive Engineers* tolling to apply. Def.'s Mem. in Supp. of Mot. for Recons. ("Def.'s Br.") at 2, ECF No. 42. Defendant cites from the text of its initial briefing on the issue:

Tellingly, Congress departed from the standard form statutory limitation period when it drafted § 154(b)(4)(A). Instead of triggering the start of the limitations period for judicial review on the date of the agency action for which review is sought—which must be final to be judicially reviewable—the limitation period of § 154(b)(4)(A) begins to run on a fixed date that is unchanged by a petition for reconsideration or any event that might affect the finality of the action subject to review.

Def.'s Br. at 5 (citing Def.'s Combined Opp'n to Pls.' Mot. for Summ. J. and Reply in Supp. of Mot. to Dismiss, ECF No. 35, at 9 (emphasis added)). Defendant claims that the Court focused on the "fixed date" language and did not address defendant's point that setting the time limit as running from the grant of the patent does not fix the commencement of the limitations period to any particular determination of a patent term adjustment.

Defendant argues that the clear and unambiguous language of the statute shows that Congress intended the 180-day limit to apply regardless of any pending motions for reconsideration. On this point, defendant cites 35 U.S.C. § 154(b)(3)(D), which states that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.” Defendant argues that “[b]ecause the court’s ruling contravenes the plain and unambiguous language of 35 U.S.C. § 154(b)(4)(A), it constitutes clear error that justifies reconsideration.” Def.’s Reply in Supp. of Mot. for Recons. (“Def.’s Reply”) at 2, ECF No. 44.

A. Timing of Patent Term Adjustment Determinations

As an initial matter, the Court finds that the PTO’s argument rests on a flawed premise. Specifically, the PTO argues that the grant of a patent is an event distinct from the PTA determination. Def.’s Br. at 4. The Court finds that, to the contrary, the patent itself embodies the agency’s final patent term adjustment determinations, encompassing the calculations for the various categories of delay. Although notice of the patent term adjustment is provided to the applicant before the grant of the patent, not all patent term adjustment determinations are final until the patent is granted.

In particular, B delay, which compensates the applicant for any time the application was pending over three years prior to the grant of the patent, is not finalized until the patent is granted. See Def.'s Mot. to Dismiss at 3, ECF No. 28. When the patent is granted, therefore, the various intermediate decisions made by the PTO regarding which patent term adjustments are appropriate are embodied within the patent. Rather than decoupling the final agency action (the PTA determination) from the trigger for the limitation period (the grant of the patent), the time period for appeal runs specifically from the PTO's final definitive statement on the PTA determinations: the patent.⁴

The Court finds that defendant's attempts to distinguish the cases cited in the Court's prior Opinion are not persuasive. In one case, the Circuit Court found that tolling applied to a 90-day limitation period that ran from the date of "promulgation or denial" of a regulation. See *Columbia Falls Aluminum Co. v. Env'tl. Prot. Agency*, 139 F.3d 914 (D.C. Cir. 1998). In the other case, the Circuit Court found that tolling applied to a 30-day limitation period that ran from the date "public notice

⁴ This relationship between the grant of the patent and the PTA determination is further supported in the regulations. See, e.g., 37 C.F.R. § 1.705(d) ("If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued").

is given" of the decision or order complained of. See *Los Angeles SMSA Ltd. P'ship v. FCC*, 70 F.3d 1358 (D.C. Cir. 1995). Defendant argues that there is a "critical distinction" between the statutes in those cases and the patent term adjustment statute. Specifically, defendant argues that in this case, the limitations period runs from a date that is independent of the agency's decision on the patent term adjustment because it runs from the date of the grant of the patent. In the two cases cited above, the limitations period runs from notice or promulgation of the underlying action being challenged. Defendant argues that in those cases, the "reconsideration request, by removing the finality of the agency action, deactivates the limitation-period triggering event, and thus changes *the date on which the limitation period starts.*" Def.'s Reply at 4. Defendant argues that, in contrast, a "request for reconsideration of a PTA determination would not deactivate the Patent statute's limitation triggering event because that date - the patent's grant date - is not affected by the finality of the PTA determination." *Id.* The Court does not find that there is any meaningful distinction between these two points, particularly in light of the Court's finding that PTO's final determinations as to the patent term adjustments are embodied in the patent itself. Thus, the filing of a motion for reconsideration would indeed "deactivate" the agency's final

determinations as to the challenged patent term adjustments embodied within that patent. Challenging a patent term adjustment need not "dislodge" or invalidate the entire patent, as the defendant appears to argue, in order for the tolling rule to apply to reconsideration of the PTO's patent term adjustment determinations. Defendant has cited no case law that would suggest otherwise.

B. Congressional Intent

The Court also disagrees with the PTO's main argument: that the "plain and unambiguous language" of 35 U.S.C. § 154(b)(4)(A) indicates that Congress intended for the tolling rule not to apply to the reconsideration of patent term adjustment decisions. Specifically, the PTO claims that the statute reflects Congress's intent for two events to occur prior to the issuance of a patent: (1) the Director's determination of a patent term adjustment; and (2) the commencement of the time for seeking reconsideration of any such determination. See Def.'s Reply at 2.

As the Court explained in its prior Opinion, this case is easily distinguishable from *Stone v. INS*, the only case the PTO has brought to the Court's attention in which the tolling rule was found not to apply. See 514 U.S. 386 (1995). In that case, the Sixth Circuit Court of Appeals had dismissed as untimely a petition for review of a deportation order. The court found

that the petitioner's filing of a motion for reconsideration with the Immigration and Naturalization Service ("INS") did not toll the running of the 90-day filing period for judicial review of deportation orders established by the Immigration and Nationality Act ("INA").

The Supreme Court affirmed, finding that Congress intended to depart from the tolling rule in the context of deportation orders. In so ruling, the Court considered two provisions of the INA. First, the Court considered Section 106(a)(1), which provides an alien with 90 days to petition for review of a final deportation order. Second, the Court considered Section 106(a)(6), which provides that "whenever a petitioner seeks review of an order under this section, any review sought with respect to a motion to reopen or reconsider such an order shall be consolidated with the review of the order." The Court found that

[b]y its terms, Section 106(a)(6) contemplates two petitions for review and directs the courts to consolidate the matters. The words of the statute do not permit us to say that the filing of a petition for reconsideration or reopening dislodges the earlier proceeding reviewing the underlying order. . . . We conclude that the statute is best understood as reflecting an intent on the part of Congress that deportation orders are to be reviewed in a timely fashion after issuance, irrespective of the later filing of a motion to reopen or reconsider.

Stone, 514 U.S. at 395.

In this case, the patent term adjustment statute does not indicate a Congressional intent to depart from the normal tolling rule. As explained above, not all patent term adjustment determinations become final prior to the issuance of a patent. In particular, B delay does not become final until the patent is granted. Accordingly, the Court finds it unlikely that Congress intended that the commencement of the time for seeking reconsideration of a patent term adjustment for B delay would begin prior to the issuance of the patent when the calculation of B delay does not become final until the patent is issued. In this context, the "notwithstanding" clause in 35 U.S.C. § 154(b)(4)(A) is more easily understood as ensuring that the issuance of a patent will not be delayed solely because a party is challenging an A delay calculation prior to the issuance of a patent.

Indeed, as argued by the plaintiffs during oral argument, the statute indicates that Congress affirmatively intended for the tolling rule to apply to judicial review of patent term adjustment determinations. July 10, 2012 Hr'g Tr. at 36. Specifically, the statute states that "Chapter 7 of title 5 shall apply" to any action for judicial review of the patent adjustment period. 35 U.S.C. § 154(b)(4)(A). The referenced provision of the APA includes 5 U.S.C. § 704, which states that

[e]xcept as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section [entitled 'Actions Reviewable'] whether or not there has been presented or determined an application for . . . any form of reconsiderations, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

The Court finds that Congress's inclusion of this reference, which immediately follows the 180-day time period for filing for judicial review of a patent term adjustment determination, is significant. In *Locomotive Engineers*, the Supreme Court found the language in 5 U.S.C. § 704 to be central to the tolling rule. The Supreme Court stated that it "has long been construed by this and other courts merely to relieve parties from the *requirement* of petitioning for rehearing before seeking judicial review (unless, of course, specifically required to do so by statute . . .) but not to prevent petitions for reconsideration that are actually filed from rendering the orders under reconsideration non-final." *Locomotive Engineers*, 482 U.S. at 284-85. This reading of 5 U.S.C. § 704 was cited again with approval by the Supreme Court in *Stone*. See 514 U.S. at 391-92. The Court finds that Congress's explicit reference to Chapter 7 of Section 5, coupled with the absence of any specific provision setting forth a separate process for judicial review, demonstrates Congress's intent for the tolling rule to apply to reconsideration of patent term adjustments.

C. Policy Implications

The Court also finds that the application of the tolling rule to patent term adjustment determinations is correct in terms of policy and efficiency. Indeed, even the PTO agrees on this point. Def.'s Reply at 1. As the Court noted in its January 27, 2012 decision, the Court finds that defendant's proposed interpretation runs contrary to the purpose of the tolling rule, which is to conserve judicial resources by putting only a final agency action before the Court. The PTO asks the Court to find that Congress affirmatively intended to impose a rather inefficient and confusing process without having made that process clear in the statute.

Under defendant's proposed interpretation, a number of inequitable scenarios are possible. If the PTO were to fail to decide an applicant's motion for reconsideration within 180 days after the grant of the patent, the applicant would be forever deprived of the opportunity to appeal that determination to a court. If that were the rule, a prudent patent applicant would then be forced to move to reconsider any patent term adjustments while simultaneously appealing those patent term adjustments in court, without providing the PTO an opportunity to first revisit its initial patent term adjustment determination.⁵ As this

⁵ The Court notes that this initial determination is made by a computer program, rather than a person. Thus, the first time a

Circuit has noted, there is always the possibility that upon the agency's reconsideration of its initial decision, the decision could be modified in a way that would obviate the need for judicial intervention. *See United Transp. Union v. Interstate Commerce Comm'n*, 871 F.2d 1114, 1117 (D.C. Cir. 1989).

Requiring the Court and the PTO to simultaneously consider the patent term adjustments in the first instance would be an inefficient use of judicial resources. *See Telestar, Inc. v. FCC*, 888 F.2d 132, 134 (D.C. Cir. 1989) (stating that it is "pointless waste of judicial energy for the court to process any petition for review before the agency . . . act[s] on the request for reconsideration"). Congress evidenced no intent to impose such a process here. Indeed, in contrast to the statute in *Stone*, there is much less need for an urgent, immediate decision on the recalculation of the patent term adjustments embodied within a patent than there would be in the case of a deportation order, which has immediate repercussions on the alien. Once a patent is granted, any adjustments to its term become relevant only at the end of that term, which is somewhere in the realm of seventeen years after the grant of the patent. The Court sees no need to create a risk of duplicative review of

person would be reviewing the patent term adjustment would be upon reconsideration. *See* Def.'s Mot. to Dismiss, ECF No. 28, at 3.

patent term adjustments under these circumstances, particularly in light of the lack of any such direction from Congress.

V. CONCLUSION

For the foregoing reasons, none of defendant's arguments have persuaded the Court that it committed error, much less clear error. Accordingly, defendant's motion for reconsideration of the Court's January 27, 2012 Memorandum Opinion and Order is **DENIED**. An appropriate Order accompanies this Memorandum Opinion.

SIGNED: Emmet G. Sullivan
United States District Court Judge
September 20, 2012